

Claims

1. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a non-immunogenic fusion protein that comprises a non-IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof, or isolated nucleic acid molecule comprising a
5 nucleic acid sequence that encodes a fusion protein that comprises a non-IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof, wherein the non-IL-15 signal peptide is from a gene that is from the same species as the IL-15.
2. The isolated nucleic acid molecule of claim 1 wherein the non-IL-15 signal peptide is an
10 IgE signal peptide.
3. The isolated nucleic acid molecule of claim 1 wherein the fusion protein consists of a non-IL-15 signal peptide linked to IL-15 protein or a functional fragment thereof.
- 15 4. The isolated nucleic acid molecule of claim 1-3 wherein said IL-15 protein or a functional fragment thereof is IL-15 protein free of IL-15 signal peptide or a functional fragment of IL-15 protein free of IL-15 signal peptide.
- 20 5. The isolated nucleic acid molecule of claim 1-4 wherein the nucleic acid sequence that encodes the IL-15 protein or functional fragment thereof is free of IL-15 Kozak region and/or IL-15 5' untranslated region and/or IL-15 3' untranslated region.

6. The isolated nucleic acid molecule of claim 1-5 further comprising a nucleotide sequence that encodes CD40L or a functional fragment thereof.

7. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes IL-15 protein or a functional fragment thereof and a nucleotide sequence that encodes CD40L or a functional fragment thereof.

8. The isolated nucleic acid molecule of claim 1-7 further comprising a nucleic acid sequence that encodes an immunogen.

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9. The isolated nucleic acid molecule of claim 8 wherein said immunogen is a pathogen antigen, a cancer-associated antigen or an antigen linked to cells associated with autoimmune diseases.

15 10. The isolated nucleic acid molecule of claim 9 wherein said immunogen is a pathogen antigen.

11. The isolated nucleic acid molecule of claim 10 wherein said pathogen antigen is from a pathogen selected from the group consisting of HIV, HSV, HCV, and WNV.

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12. The isolated nucleic acid molecule of claim 1-11 wherein IL-15 coding sequences are free of IL-15 signal peptide.

13. The isolated nucleic acid molecule of claim 1-12 wherein IL-15 coding sequences are free of IL-15 Kozak region and/or IL-15 5' untranslated region and/or IL-15 3' untranslated region

5 14. The isolated nucleic acid molecule of claims 1-13 wherein said isolated nucleic acid molecule is a plasmid.

15. The nucleic acid molecule of claims 1-13 incorporated into a viral vector.

10 16. A composition comprising a nucleic acid molecule of claim 1-15 and a nucleic acid molecule that comprises a nucleic acid sequence that encodes an immunogen.

17. The composition of claim 16 wherein said immunogen is a pathogen antigen, a cancer-associated antigen or an antigen linked to cells associated with autoimmune diseases.

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18. The composition of claim 17 wherein said immunogen is a pathogen antigen.

19. The composition of claim 18 wherein said pathogen antigen is from a pathogen selected from the group consisting of HIV, HSV, HCV, and WNV.

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20. A composition comprising a nucleic acid molecule of claim 1-19 and a nucleic acid molecule further comprises a nucleotide sequence that encodes CD40L.

21. An injectable pharmaceutical composition comprising the nucleic acid molecules of claims 1-15 or the composition of claims 16-20.

22. An recombinant vaccine comprising the nucleic acid molecules of claims 1-13.

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23. The recombinant vaccine of claims 22 wherein said recombinant vaccine is a recombinant vaccinia vaccine.

10 24. A live attenuated pathogen wherein comprising the nucleic acid molecules of claims 1-13.

25. A non-immunogenic fusion protein that comprises a non-IL-15 signal sequence linked to an IL-15 protein sequence or a fusion protein that comprises a non-IL-15 signal sequence
15 linked to an IL-15 protein sequence wherein the non-IL-15 signal sequence is of the same species as the IL-15 protein sequence.

26. The fusion protein of claim 25 wherein the non-IL-15 signal sequence is an IgE signal sequence.

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27. The fusion protein of claim 25 or 26 consisting of a non-IL-15 signal sequence linked to an IL-15 protein sequence.

28. The fusion protein of claims 25-27 wherein the IL-15 protein sequence is free of IL-15 signal sequence.

29. A composition that comprises a nucleic acid molecule that comprises: a nucleic acid
5 sequence that encodes IL-15 protein and a nucleic acid molecule that comprises a nucleotide sequence that encodes CD40L protein.

30. The composition of claim 29 further comprising a nucleic acid sequence that encodes an immunogen.

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31. The composition of claims 29 or 30 wherein said immunogen is a pathogen antigen, a cancer-associated antigen or an antigen linked to cells associated with autoimmune diseases.

32. The composition of claim 31 wherein said immunogen is a pathogen antigen.

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33. The composition of claim 32 wherein said immunogen is a pathogen antigen from a pathogen selected from the group consisting of HIV, HSV, HCV, and WNV.

34. The composition of claims 29-33 wherein the isolated nucleic acid molecules are
20 plasmids.

35. A method of modulating an immune response in an individual comprising administering to said individual a composition of claims 58 or 63.

36. A method of inducing an immune response in an individual against an immunogen comprising administering to said individual a composition of claims 59, 62 or 64-67.
- 5 37. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences where in the IgE signal peptide and the non-IgE protein sequences are derived from the same species of animal.
- 10 38. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the non-IgE protein is an enzyme or functional fragment thereof.
39. An isolated nucleic acid molecule comprising a nucleic acid sequence that encodes a
15 fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the non-IgE protein is an immunomodulating protein or functional fragment thereof.
40. The isolated nucleic acid molecule of claim 39 wherein the fusion protein consists of an
20 IgE signal peptide linked to an immunomodulating protein or functional fragment thereof.
41. The isolated nucleic acid molecule of claims 39-40 wherein the IgE signal peptide and the non-IgE protein sequences are derived from the same species of animal.

42. The isolated nucleic acid molecule of claims 39-41 wherein said isolated nucleic acid molecule is a plasmid.

43. The nucleic acid molecule of claims 39-41 incorporated into a viral vector.

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44. An injectable pharmaceutical composition comprising the nucleic acid molecules of claims 39-41.

45. A recombinant vaccine comprising the nucleic acid molecules of claims 39-41.

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46. A live attenuated pathogen comprising the nucleic acid molecules of claims 39-41.

47. A fusion protein comprising an IgE signal peptide linked to non-IgE protein wherein the IgE signal peptide and the non-IgE protein are derived from the same species of animal.

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48. A fusion protein comprising an IgE signal peptide linked to non-IgE protein wherein the non-IgE protein is an enzyme or a functional fragment thereof.

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49. The fusion protein of claim 47 wherein the non-IgE protein sequence is an immunomodulating protein or a functional fragment thereof.

50. The fusion protein of claim 47 consisting of an IgE signal peptide linked to an immunomodulating protein or a functional fragment thereof

51. The fusion protein of claims 49-50 wherein the IgE signal peptide and the non-IgE protein are derived from the same species of animal.

5 52. An in vitro cell culture that comprises cells that comprise a nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the nucleic acid sequence is operably linked to regulatory elements required for expression in said cells.

10 53. A method of preparing a non-IgE protein comprising culturing cells that comprise cells that comprises cells that comprise a nucleic acid molecule comprising a nucleic acid sequence that encodes a fusion protein that consists of an IgE signal peptide linked to non-IgE protein sequences wherein the nucleic acid sequence is operably linked to regulatory elements required for expression in said cells under condition necessary for fusion protein
15 expression for a period sufficient for said cells to express said fusion protein.